1.0 PURPOSE

This policy is designed to ensure that good clinical practice will be followed for the supplying and handling of study products and that study products are only used for participants enrolled in a Division of AIDS (DAIDS) funded and/or sponsored clinical trial.

2.0 SCOPE

This document represents the minimum acceptable standards for pharmacies at clinical research sites utilizing study product(s), and conducting DAIDS funded and/or sponsored clinical trials outside of the HIV/AIDS Clinical Trials Networks.

Additional requirements are likely to pertain at sites participating in multi-center clinical trials, such as those performed through the DAIDS-sponsored HIV/AIDS Clinical Trials Networks and/or clinical trials evaluating investigational agents.

3.0 BACKGROUND

Within DAIDS, the Pharmaceutical Affairs Branch (PAB) establishes and oversees policies for clinical research site pharmacies conducting DAIDS sponsored or funded domestic and international clinical research trials. These policies include the development of standard operating procedures, quality assurance measures and accountability processes, prepared by the Pharmacist of Record, for the management of study products.

4.0 DEFINITIONS

Division of AIDS (DAIDS) sponsored –DAIDS is responsible for the management (including submission of the Investigational New Drug Application (IND) to FDA and initiation of the study) and oversight for the trial.

Division of AIDS (DAIDS) funded – DAIDS is providing financial support for trial or study.

Investigator of Record (IoR) – The person responsible for the conduct of the clinical trial, at a clinical research site. This person is the signatory for the Form FDA 1572 (IND studies), or IoR Agreement (Non-IND studies). Written delegation of authority for specific study responsibilities may be given to qualified individuals.

Principal Investigator (PI) – The qualified person designated by the applicant institution to direct the research. PIs oversee the scientific and technical aspects of a grant and the day-to-day management of the research.

Pharmacy – Any facility, building, or room used to perform one or more of the following functions: storage, preparation, dispensing, management of study products, (example: dispensary, drug storage unit, drug store).

Study products – Any drug, biologic, vaccine, radiopharmaceutical, item or device that are either provided for the study or identified in the protocol as being a study product.

Pharmacist of Record – A licensed/registered pharmacist who performs the day to day pharmacy activities and study product management including but not limited to the procurement, storage, preparation, dispensing and final disposition of study products for DAIDS funded and/or sponsored clinical trial(s) must be identified as the Pharmacist of Record.

Pharmacy Equipment – Apparatus (device or machinery) that is utilized to ensure the physical and scientific integrity of the study product during shipment, storage, handling, and preparation. Examples of pharmacy equipment are; biological safety cabinets, refrigerators, -20 C freezers, -70 C freezers, air conditioners, dehumidifiers, thermometers, vortex machines, temperature alarm systems, limited access/security systems (alarms, key lock) in study product and pharmacy regulatory file storage areas, locking file and storage cabinets, shelving, counting trays for tablets and capsules, graduated cylinders, spatulas, study product containers, fax machines, computers, and printers.

Pharmacy Ancillary Supplies – Any materials or tools that may be used in a pharmacy to perform and support the day to day activities and functions of the pharmacist, such as needles and syringes, oral syringes, prescription vials and lids, gowns, masks, IV solutions, diluents

For additional definitions see DAIDS glossary.

5.0 RESPONSIBILITIES

The IoR is responsible for ensuring that the study products needed for the research activities are available for the duration of the study and that the pharmacy has the equipment and ancillary supplies needed to perform the pharmacy activities for the conduct of the clinical trial at the clinical research site.

The IoR is responsible for identifying authorized prescribers.

The IoR is responsible for ensuring that the study products are used in accordance with the approved protocol.

The Pharmacist of Record is responsible for executing the required pharmacy activities.

It is the responsibility of the IoR and the Pharmacist of Record to be knowledgeable of all applicable laws and regulations.

The IoR is responsible for establishing a communication system for study staff so that the protocol and all protocol related information is provided to the Pharmacist of Record systematically and in a timely fashion.

The Pharmacist of Record is responsible for establishing a system for reporting and documenting discrepancies with regards to study product dispensing or management.

The PI and IoR are responsible for ensuring that all site personnel involved in the conduct of any DAIDS funded and/or sponsored clinical trial are knowledgeable of the DAIDS standards for pharmacy activities to ensure the proper conduct of the trial.

6.0 POLICY

- The pharmacy must have written Policies and Procedures that govern the receipt, storage, inventory process, accountability, record keeping, preparation, distribution, labeling, handling, dispensing and final disposition of study products in accordance with applicable regulations.

- Medication orders or prescriptions and administration of study products must be guided by Policies and Procedures.

- Authorized prescribers must be identified through the use of either the Form FDA 1572 or DAIDS Investigator of Record Agreement.

- The Pharmacist of Record must maintain readily accessible files containing communications with clinical research site staff and others (e.g. DAIDS staff).

- The Pharmacist of Record must organize study documents to ensure accurate recording, verification and retrieval of information.

- Study product accountability records must be available for inspection and copying by a properly authorized employee or representative of the DAIDS or the FDA.

- The study product(s) must be stored as indicated in the label or other product information in a limited access area separate from other agents and must be inventoried on a monthly basis.

- The Pharmacist of Record must maintain the scientific integrity of studies by managing access to treatment-assignment records and study products in blinded studies and by ensuring that the correct study product was dispensed. The Pharmacist of Record, PI, IoR, and sponsor must agree on a procedure for unblinding treatment assignment in emergencies.

- The Pharmacist of Record must ensure that the study participant is dispensed the correct dose of the proper drug, biologic, vaccine or radiopharmaceutical as defined by the protocol through the implementation of a quality management program.

- The Pharmacist of Record must have a system in place that ensures that a participant on a study has signed an informed consent before dispensing any protocol related study product(s). Study products must be dispensed only to participants who have signed an informed consent for the study.

- The pharmacy must have a study product recall system for identifying, retrieving, and returning study products that:
    - are recalled by manufacturer or supplier
    - are known to be expired or outdated
    - have been dispensed to study participants

- There must be a system in place to ensure that all study products dispensed to study participants will not have gone beyond the expiration date at the end of the treatment period for the prescription.

7.0 REFERENCES

International Conference on Harmonisation, Guidance for Industry, E6 Good Clinical Practice: Consolidated Guideline

U.S. Code of Federal Regulations, Title 21, Part 312
http://www.access.gpo.gov/nara/cfr/waisidx_05/21cfr312_05.html

Joint Commission International Accreditation Standards for Hospitals, 2002 by the Joint Commission on Accreditation of Healthcare Organizations.

8.0 INQUIRIES

Questions and comments regarding this policy may be directed to the OPCRO Policy Group at:

NIAIDOPCROPOLICYGROUP@mail.nih.gov

9.0 AVAILABILITY

This policy is available electronically at the following URL:
http://www3.niaid.nih.gov/research/resources/DAIDSClinRsrch/Default.htm

The signed original is maintained in the OPCRO policy office.

10.0 CHANGE SUMMARY

Version #	Date	Replaces	Date of Revision	Rationale for Revision/Retirement
1.0	14 JUL 06	N/A	N/A	N/A

11.0 APPENDICES

None.

12.0 APPROVAL

	Signature	Program/Branch	Date
Authorized By:	Richard Hafner Richard Hafner, MD Director	Office for Policy in Clinical Research Operations	July 14, 2006